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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/981,337	10/16/2001	Donald T. Shannon	VAS-5041DIV2	6517

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EXAMINER	
PELLEGRINO, BRIAN E	
ART UNIT	PAPER NUMBER
3738	7

DATE MAILED: 05/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

GL

Office Action Summary	Application No.	Applicant(s)	
	09/981,337	SHANNON ET AL.	
	Examiner	Art Unit	
	Brian E Pellegrino	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 February 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-80* is/are pending in the application.

4a) Of the above claim(s) *22,23,35,36 and 41-80* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21,24-34 and 37-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 October 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Species II, an internally stented PTFE graft and Species A, a self-expanding stent and Species 3) polymer tube placed around elongate members in Paper No. 6 is acknowledged. The traversal is on the ground(s) that Species I is a combination of Species II and III and that the search is not a serious burden on the examiner. This is not found persuasive because Applicant's did not submit evidence or identify on the record that the species are obvious variants of one another and did not clearly admit on the record that this is the case.

Claims 22,23,35,36,41-80 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 6.

The requirement is still deemed proper and is therefore made FINAL.

Priority

This application repeats a substantial portion of prior Application No. 09/358350, filed 7/21/99, but claims additional disclosure not presented in the prior application. Since this application names an inventor or inventors named in the prior application, it may constitute a continuation-in-part of the prior application. Should applicant desire to obtain the benefit of the filing date of the prior application, attention is directed to 35 U.S.C. 120 and 37 CFR 1.78.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "means for anchoring, i.e. protrusions" must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required:

1) means for anchoring stent and covering, i.e. protrusions.

2) fibril lengths up to 300μ.

3) fibril lengths up to 200μ.

4) fibril lengths up to 100μ.

5) fibril lengths up to 50μ.

6) fibril lengths up to 5μ.

7) shape memory alloy material that can alternately exist in a first and second crystalline state.

8) a shape memory alloy that has 51-59% nickel and the rest titanium.

9) a shape memory alloy that has 0.25% chromium and 51-59% nickel and the rest titanium.

10) stent formed from plastic members, i.e. PTFE, FEP, PET, etc.

11) an article of manufacture, comprising packaging and a stent graft.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6, 15 and 30 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. On page 7, lines 12-15 the Applicants state that the "elastomer covering" or outer layer is ePTFE. The disclosure does not mention other polymers for the covering. The stent may be coated with other polymers, but this is a different coating than the graft material. Thus the subject matter of claim 6 is new matter.

On page 18 of Applicant's specification, lines 27-29 state that two wrappings or layers of tape have a thickness of approximately 0.1 inches. If each tape wrapping is approximately equal in thickness, they would have a thickness of about 0.05 inches. It is not evident how the tape thickness can be less than 0.015 inches as in claims 15 and 30?

Claims 39,40 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. On page 5 of the specification, the Applicants mention uses of stent grafts, however, there are no facts to show that the stent graft of the claimed invention was used in any treatment for cardiovascular disease. Therefore, claim 39 is not enabled by the specification. Regarding claim 40, there are many ways to package devices, thus because there is no support in how Applicants achieved "an article of manufacture comprising packaging" this claim is not enabled by the specification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4,6-8,11-16,20,21,29-32,39 are rejected under 35 U.S.C. 102(b) as being anticipated by Myers et al. (WO 95/05132). Fig. 6 shows a cylindrical stent **10** formed with a tubular covering **20**. Myers discloses that the tubular covering is porous PTFE, page 3, lines 14-15. Regarding claim 2, Fig. 9 shows a multiplicity of wire members braided and has lateral openings. With respect to claim 3, the stent can be anchored to the covering by different means, including sutures, page 12, lines 12-20.

Fig. 8 shows the stent wire members "fixedly embedded" in the covering. With respect to claims 8 and 12, Myers discloses the PTFE has fibrils with lengths about 50μ, page 12, lines 25-27. Myers additionally states the fibril lengths can be about 5 to about 100μ in length, page 6, lines 29-32. Regarding claims 14-16,31 Myers also discloses helically wrapping the stent with tape having a width *less* than 1 inch, a thickness *less* than 0.015 inch and a density *less* than 1.6 g/cc, page 12, lines 24-26. Regarding claims 20,21, Myers discloses the stent is self-expanding and that Nitinol (nickel-titanium) can be used for the stent, which inherently can exist in two crystalline states, page 5, lines 13-15 and page 7, line 10. Myers additionally discloses the covering is less than 0.1 inch, page 12, lines 23,24. The device is fully capable of being implanted to treat cardiovascular disease since there is no standard as to what is considered "effective" in ameliorating the disease.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 9,10,17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Myers et al. '285. Myers is explained supra.

Claims 9,10 -However, Myers et al. do not disclose fibrils with a length measuring up to about 200 or 300μ. It would have been an obvious matter of design choice to

modify the fibril lengths of Myers, since applicant has not disclosed that using 200 or 300μ provides any advantage, or solves a stated problem, or is used for any particular purpose. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the fibril lengths taught by Myers et al. or the claimed 200 or 300μ in claim(s) 9,10 because both Myers and the claimed lengths perform the same function of permitting tissue ingrowth.

Claims 17-19 -However, Myers et al. do not disclose applying 6-8 revolutions or layers of tape and in opposite directions. It would have been an obvious matter of design choice to modify the number of wrappings of tape and the directions applied on the stent, since applicant has not disclosed that using 8 layers or layering the tape in opposite directions provides any advantage, or solves a stated problem, or is used for any particular purpose. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the number of wrappings taught by Myers et al. or the claimed 8 layers and opposing directions in claim(s) 17-19 because both Myers and the claimed number of layers and application of these layers perform the same function of providing a blood impermeable lining.

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Myers (WO 95/05132) in view of Zadno-Azizi et al. (5907893). Myers is explained supra. However, Myers et al. do not disclose the stent having about 51% nickel and the remainder titanium. Zadno-Azizi et al. teach that stents can be made with about 51% nickel and the rest titanium having good shape memory and self expanding properties, col. 9, lines 13-20. It would have been obvious to one of ordinary skill in the art to use a

51% nickel-titanium stent as taught by Zadno-Azizi with the stent-graft of Myers in order to provide the ability to self-expand when deployed in the vessel.

Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Myers (WO 95/05132) in view of Zadno-Azizi et al. (5907893) and McCrea et al. (6451047). Myers is explained supra. However, Myers et al. do not disclose the stent having about 0.25% chromium, about 51% nickel, and the remainder titanium. Zadno-Azizi et al. teach that stents can be made with about 51% nickel and the rest titanium having good shape memory and self expanding properties, col. 9, lines 13-20. McCrea et al. teach that NiTi alloys can have small percentages of ternary elements added, such as chromium, col. 4, lines 14-24. It would have been an obvious matter of design choice to modify the percent of chromium added as taught by McCrea et al. with the stent-graft of Myers as modified by Zadno, since applicant has not disclosed that using 0.25% chromium with the NiTi alloy provides any advantage, or solves a stated problem, or is used for any particular purpose. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the percent of chromium taught by McCrea in the stent-graft of Myers in view of Zadno using an about 51% nickel-titanium stent because both Myers as modified by Zadno and McCrea and the claimed 0.25% chromium alloy stent perform the same function of providing the ability to lower the transformation temperature and also have increased radiopacity.

Claims 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Myers (WO 95/05132) in view of Trerotola et al. (5591226). Myers is explained supra. However, Myers does not disclose a helically braided, plastic member stent. Trerotola

et al. teach that plastic can be used in a helically braided stent, col. 2, lines 23-26. It would have been obvious to one of ordinary skill in the art to use plastic members for the braided stent and to have a helical braid as taught by Trerotola et al. in the stent-graft of Myers et al. in order to provide a flexible, less radiopaque device and has greater support coverage.

Claims 5,33,34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Myers (WO 95/05132) in view of Palmaz (4776337). Myers is explained supra. However, Myers does not disclose a coating formed on the stent or means to anchor such as protrusions in a covering on the stent. Palmaz teaches to place a polymer coating such as PTFE on the stent and to have projections on the coating to anchor the stent with the coating, col. 9, lines 26-42. It would have been obvious to one of ordinary skill in the art to use a coating on the stent and to have projections on the coating to anchor to the stent as taught by Palmaz with the stent-graft of Myers in order to provide a smooth surface thereby reducing the chance of restenosis.

Claims 37,38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Myers (WO 95/05132) in view of An et al. (5545211). Myers is explained supra. However, Myers does not disclose a coating formed on the stent elongate members. An et al. teach that a polymer coating can be placed around the wires, col. 4, lines 1, 7. An also teaches that the coating prevents unwanted tissue growth and restenosis, col. 4, lines 10-12. It would have been obvious to one of ordinary skill in the art to use a coating on the stent members as taught by An et al. with the stent-graft of Myers in

order to provide a stent-graft that would not require subsequent angioplasty procedures because restenosis was prevented.

Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over Myers (WO 95/05132) in view of Bley et al. (5765682). Myers is explained supra. However, Myers does not disclose a packaged device. Bley et al. teach that shape memory medical devices, such as stents are preserved in packages that restrain them from prematurely expanding, col. 3, lines 43-50, col. 4, lines 1-5. It would have been obvious to one of ordinary skill in the art to use a packaging material taught by Bley et al. with the stent-graft of Myers et al. in order to preserve and prevent premature expansion of the stent-graft so that it can be optimally effective at the time of implantation. It would have been obvious to have a label with instructions on the package since labels are well known in the medical art and since there is no standard as to what is considered "effective" in ameliorating a cardiovascular disease it can be said the device would be effective.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1,2,7,14-21,26-34,37,38 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8,10,12-15,18-23,26,27 of U.S. Patent No. 5928279. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the pending application are merely broader than the claims patented before. The patented claims anticipate the application claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Pellegrino whose telephone number is (703) 306-5899. The examiner can normally be reached on Monday-Thursday from 9am to 6:30pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached at (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-2708.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Brian Pellegrino

05/04/03 TC 3700, AU 3738

Brian E. Pellegrino